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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/796,215	03/09/2004	Scott T. Moore	10000-353	2716

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EXAMINER	
LANG, AMY T	

ART UNIT	PAPER NUMBER
3731	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/796,215	MOORE ET AL.	
	Examiner	Art Unit	
	AMY T. LANG	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 January 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-28 and 35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-28 and 35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This office action replaces the non-final mailed 10/27/2009 since Acosta et al. (US 7,182,779 B2) is not proper as prior art for the teaching of PTFE.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. **Claims 1, 2, 4, 6-12, 14-28, and 35** are rejected under 35 U.S.C. 103(a) as being unpatentable over Moore (US 2001/0049547 A1).

With regard to **claims 1, 4, and 11**, Moore discloses a pusher assembly (see entire document) comprising a catheter (11), a first tubular portion (13) and a second tubular portion (12). The first tubular portion is comprised of non-rigid polymer ([0014]). The second tubular portion extends distally from the first tubular portion and, as shown in Figure 1, comprises a flexible section and a stent carrying section ([0014]). A pusher

member (14) is located proximal of the stent on the second tubular portion and urges the stent from the catheter ([0015]). The pusher member comprises a polymer and has a proximal taper ([0015]; Figure 1). Furthermore, the pusher member is inherently adapted to be positioned at an acute bend in a patient's body and absorb preload pressure form the stent. As shown in Figure 1, the outside diameter of the first tubular portion (13) is less than the inside diameter of the catheter (11).

Although Moore teaches the pusher member comprises a polymer, Moore does not specifically teach the pusher member as configured to conform to a distal end of the stent.

Moore teaches that that pusher assembly (30) is comprised of polytyerekerketone (PEEK) ([0004]). The pusher assembly (30) includes the pusher member (14) and Moore teaches that the pusher member may comprise a polymer ([0015]). Therefore, it would have been obvious at the time of the invention for the pusher member (14) to also comprise the PEEK material. This polymer material would conform to the shape of the stent which would result in better positioning of the stent during deployment. Therefore the pusher member would be configured to conform to a distal end of the stent and reduce the likelihood of partial deployment.

With regard to **claims 2 and 12**, the flexible section of the second tubular portion has a preselected length depending on the application ([0016]). The region comprising the greatest likelihood of a kink intrinsically corresponds to the region of greatest flexibility.

With regard to **claims 6 and 18**, as shown in Figures 1 and 5, the second tubular member has a smaller outer diameter than the first tubular portion.

With regard to **claims 7-9, 19-21, and 24-26**, the second tubular portion is further disclosed as comprising a braided polyimide tubing ([0014]).

With regard to **claims 10 and 22**, the stent carrying section and the flexible section are comprised of a single continuous element ([0014]). The sent is positioned along the sent carrying section between the pusher member (14) and a tapered distal tip (16).

With regard to **claim 14**, as shown in Figure 1, the proximal end of the stent is received by the pusher member and inherently absorbs preload pressure.

With regard to **claims 15 and 23**, as shown in Figure 1, the pusher member (14) comprises a face and a proximal taper. Additionally, as shown in Figure 5, the second tubular portion comprises a thinner wall than the first tubular portion.

With regard to **claims 16 and 28**, the stent is self-expanding ([0012]).

With regard to **claim 17**, as shown in Figure 1, the pusher assembly and stent are slideably disposed in the catheter (11).

With regard to **claim 27**, the stent carrying section is distal of the flexible section and extends to the distal tip.

With regard to **claim 35**, as shown in Figure 5, the second tubular portion extends the entire length of the first tubular portion ([0016]).

4. **Claims 1-4 and 6-28** are rejected under 35 U.S.C. 103(a) as being unpatentable over Ravenscroft (US 5,702,418) in view of Wilson et al. (US 6,425,898 B1) and Gellman et al. (US 2003/0176831 A1).

With regard to **claims 1, 4, and 11**, Ravenscroft discloses a pusher assembly of a stent delivery system (see entire document) comprising a catheter (11), a first tubular portion (15 or 16), and a second tubular portion (17). The first tubular portion comprises PEBAX or is disclosed as flexible, which clearly overlaps the instantly claimed non-rigid polymer (column 5, lines 23-26. 29-30). As shown in Figures 5, 1, and 4, the second tubular portion comprises a distal stent carrying section and a proximal section, located proximal of the stent carrying section. The second tubular (17) is disclosed as flexible so that the proximal section clearly overlaps the instantly claimed flexible section. Furthermore, it is the examiner's position that the second tubular portion distally extends from the first tubular portion, as shown in Figure 5. Additionally, the outside diameter of the first tubular portion (15 or 16) is less than the inside diameter of the catheter (11) (Figure 5).

Ravenscroft further discloses rings (23) placed around the stent to urge the stent distally when advanced form the catheter. However, Ravenscroft does not specifically disclose a soft pusher member having a tapered proximal surface to urge the stent distally.

Wilson et al. (hereinafter Wilson), as shown in Figure 5, discloses a catheter assembly comprising a distal stent carrying section. Immediately proximal to the stent carrying section is pusher member (21 and 22). Wilson teaches that the pusher

member contacts the stent and helps to urge the stent out of the sheath when deployed into the patient at the target site (column 5, lines 58 through column 6, line 21). The pusher member is further disclosed as made from any material known in the art which encompasses polymer materials. As shown in Figure 5, the pusher member (21 and 22) tapers proximally and is intrinsically configured to be positioned at an acute bend in a patient's body and absorb preload pressure.

If Applicant were to argue that the taper of the pusher member is not gradual, the instant disclosure describes this parameter as merely preferable and does not describe it as contributing any unexpected result to the pusher member. As such this parameter is deemed a matter of design choice (lacking in any criticality) and well within the skill of the ordinary artisan, obtained through routine experimentation in determining optimum results.

Wilson teaches that the pusher member advantageously pushes the stent during deployment while preventing the stent from proximally retracting (column 6, lines 2-6). Therefore, since Ravenscroft discloses a pusher member and Wilson discloses a specific pusher member that is advantageous, it would have been obvious to one of ordinary skill in the art at the time of the invention for Ravenscroft to utilize the pusher member of Wilson.

However, Wilson does not specifically disclose the pusher member as conforming to a distal end of the stent. Gellman et al. (hereinafter Gellman) also discloses a pusher member (1015) that engages the proximal end of the stent to urge the stent from the catheter (Figure 10). The pusher member advantageously conforms

to the shape of the stent which would achieve better positioning during deployment ([0013]). Therefore, the pusher member would be configured to conform to a distal end of the stent and reduce the likelihood of partial deployment.

With regard to **claims 2 and 12**, Ravenscroft teaches the pusher assembly is utilized for endoscopic delivery of stent to a patient (column 1, lines 6-9). Therefore, it would have been obvious to one of ordinary skill in the art for each component, specifically the flexible section, to comprise a preselected length that is proper for the designated procedure. The region comprising the greatest likelihood of a kink intrinsically corresponds to the region of greatest flexibility.

With regard to **claims 3 and 13**, the pusher member of Wilson is further disclosed as comprising a radiopaque filler (column 6, lines 19-21).

With regard to **claims 6 and 18**, as shown in Figure 5 of Ravenscroft, the second tubular portion (17) comprises a smaller outer diameter than the first tubular portion (15 or 16).

Withy regard to **claims 7-9, 19-21, and 24-26**, Ravenscroft does not specifically disclose the second tubular member as comprising a metal-reinforced polymer material or as Nitinol. Wilson teaches the distal end of the tubular shaft (10) comprises a polymer material reinforced with metal braided wires or Nitinol (column 5, lines 27-35). This gives the tubular member shaft the necessary flexibility and strength to navigate vessels and deploy the stent (column 5, lines 38-44). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention for the distal end of

the tubular member, the second tubular member, to comprise a polymer reinforced with metal ort Nitinol, a nickel-titanium alloy

With regard to **claims 10 and 22**, as shown in Figure 5 of Ravenscroft, the stent carrying section and the flexible section are comprised of a single continuous element. The sent is positioned along the sent carrying section between the soft pusher member and a tapered distal tip (13).

With regard to **claim 14**, Ravenscroft in view of Wilson would produce a pusher assembly wherein the proximal end of the stent is received by the pusher member and intrinsically absorbs preload pressure.

With regard to **claims 15 and 23**, as shown in Figure 4 of Wilson, the pusher member (22 and 21) comprises a face, the distal portion of 22, which has a diameter equal to the preloaded stent. Ravenscroft teaches the second tubular portion as thin and the first tubular portion as thick (column 5, lines 3-6). Therefore, the second tubular portion has a thinner wall than the first tubular portion.

With regard to **claims 16 and 28**, Ravenscroft further discloses the stent as self-expanding (column 4, lines 60-62).

With regard to **claim 17**, as shown in Figures 5, 1, and 4 of Ravenscroft, the pusher assembly and stent are slideably disposed in the catheter (11).

With regard to **claim 27**, the stent carrying section of Ravenscroft is distal of the flexible section and extends to the distal tip.

5. **Claims 3 and 13** are rejected under 35 U.S.C. 103(a) as being unpatentable over Moore (US 2001/0049547 A1) as applied to claims 1 and 11, and further in view of Wilson (US 6,425,898 B1).

Moore discloses the invention substantially as claimed but fails to teach the pusher member comprising a radiopaque filler.

Wilson also discloses a push member to urge the stent from the catheter. The pusher member comprises a radiopaque filler to aid in positioning the stent at the target site (column 6, lines 19-21). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention for the pusher member of Moore to also comprise a radiopaque filler for the advantage disclosed by Wilson.

6. **Claims 4 and 5** are rejected under 35 U.S.C. 103(a) as being unpatentable over Moore (US 2001/0049547 A1) as applied to claim 1 above, and further in view of Boylan et al. (US 2001/0049549 A1).

Moore discloses a pusher assembly, as described above, comprising a pusher member (14) formed of PEEK. However, Moore does not specifically disclose the pusher member as formed of PTFE.

Boylan et al. (hereinafter Boylan) teaches that both PEEK and PTFE are well known in the art and either one can be used in place of the other when used in the catheter art ([0077]). Therefore, it would have been obvious at the time of the invention for Moore to use PTFE instead of PEEK for the pusher member (14) of the catheter.

7. **Claim 35** is rejected under 35 U.S.C. 103(a) as being unpatentable over Ravenscroft (US 5,702,418) in view of Wilson (US 6,425,898 B1), Gellman (US 2003/0176831 A1), and Chew (US 2004/0215331 A1).

Ravenscroft in view of Wilson and Gellman discloses the invention substantially as claimed but fails to teach the second tubular member (17) as extending along the entire length of the first tubular member (15 or 16).

Chew discloses a catheter with multiple tubular members. As shown in Figure 20, an inner tubular member (336) extends the length of middle tubular member (334) which extends the length of outer tubular member (332) ([0132]). Inner tubular member forms a guidewire lumen ([0132]). Since Ravenscroft also discloses a guidewire and multiple tubular members, it would have been obvious to one of ordinary skill in the art at the time of the invention for the second tubular portion (equivalent to an inner tubular member) to extend the length of the first tubular portion (equivalent to a middle tubular member) and form a guidewire lumen.

Response to Arguments

8. Applicant's arguments filed 08/14/2008 have been fully considered but they are not persuasive.

Specifically, applicant argues (A) that Wilson does not disclose a tapered pusher member.

With respect to argument (A), the pusher member of Wilson comprises members 21 and 22. As shown in Figure 5, the members become smaller in diameter from the

distal to proximal end. Therefore, the pusher member diminishes and becomes progressively smaller. This diminish is gradual since member 21 is only slightly smaller than member 22. However, it Applicant were to continue to argue that the pusher member is not tapered gradually, this limitation is an obvious design choice.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AMY T. LANG whose telephone number is (571)272-9057. The examiner can normally be reached on M-F 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

05/04/2009
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